STEP-BY-STEP GUIDE ON
COSMETIC PRODUCT NOTIFICATION

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Introduction

Companies responsible for placing the cosmetic products in Singapore must notify the Health Sciences Authority (HSA) and receive an acknowledgement of notification before placing the products in the local market. The product notification is submitted via HSA online system PRISM (Pharmaceutical Regulatory Information System).

In order to access PRISM, please apply for CRIS (Client Registration and Identification Service) Company Account via the following website:
http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/CRIS.html

How can my company apply for a cosmetic product notification?

a) To apply for a cosmetic product notification, please use **Internet Explorer 8.0 and above** and go to the following website:
http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/PRISM_e-services/Cosmetic_Products_Oral_Dental_Gums.html

b) Click on "**Cosmetic products / Oral dental gums**"

c) Click on "**Apply for cosmetic product notification**"

d) Thereafter, you will be directed to the following page:

- Login using CorpPass, SingPass (ends on 31 Dec 2017) or HSA Pin

e) Upon successful authentication, a welcome page will be shown. Click "**Accept/Continue**" to proceed with the eService. You will be directed to the online application form. The application form consists of **6** sections:

1	Particulars of local company responsible for placing the cosmetic product in the market
2	Particulars of person authorised to represent the local company
3	Particulars of manufacturer(s)
4	Particulars of product
5	Supporting document(s)
6	Declaration, validation, confirmation, & payment

* It is recommended for users to fill in the application form details in a systematic manner * PLEASE FILL IN ALL SECTIONS IN ENGLISH

To note:
- A HSA Pin holder or a drafter is able to fill up the form only. He or she is not authorised to submit the notification.
- A submitter can perform both form filling and notification submission
- CRIS Administrator can draft and submit a cosmetic product notification

(1)   Section 1: Particulars of local company responsible for placing the cosmetic
        product in the market

a. Ensure that the details are accurate and corresponds to your company
   details. Fill in the Billing Address if the answer is "No" to section 1.6
b. Click "**Next**" to proceed to the next section

** If the populated information of local company has been changed and the UEN number
remains the same, please click "Amend Company Information" under the following weblink to
change the information after you have submitted the notification **
http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/PRISM_e-
services/Cosmetic_Products_Oral_Dental_Gums.html

(2)   Section 2: Particulars of person authorised to represent the local company

a. Fill in the details for:
   ✓ Applicant's name
   ✓ NRIC/FIN
   ✓ Telephone number
   ✓ Indicate Preferred Mode of Communication
   ✓ Designation in Company

b. Click on "**Next**" to proceed to the next section

(3)   Section 3: Particulars of manufacturer

PQ1001 APPLICATION FOR COSMETIC PRODUCT NOTIFICATION

Fill in the application form	Guideline	Help

1. Particulars of Local Company Responsible for Placing the Cosmetic Product in the Market
2. Particulars of Person authorised to represent the local company
3. Particulars of Manufacturer

4. Particulars of Product
5. Supporting Attachments
6. Confirmation

Special Symbol   Attach   Save

Previous Next

Fields marked with an asterisk * are mandatory.

3. Manufacturer Details

3.1 Name : *

3.2 Manufacturer Address

3.2.1 Address Type : *   ⦿ Local   ○ Overseas

3.2.2 Postal Code : *   (Retrieve Address)

3.2.3 Block / House No :   3.2.4 Level – Unit :   #   –

3.2.5 Street Name :

3.2.6 Building Name :

3.2.7 Country :   SINGAPORE

3.3 Tel :   3.4 Fax :

New Save

A Manufacturer is a company which is engaged in any process carried out in the course of making the cosmetic product. The manufacturing process includes all operations of purchase of starting materials, bulk intermediates and products, formulation and production (such as grinding, mixing, encapsulation and/or packaging), quality control, release, storage and distribution of cosmetic products and the related controls.

Previous Next Reset

a. Provide the name of the Manufacturer
b. If it is a local manufacturer, fill in the **Postal Code** and click on "**Retrieve Address**". The data for Blk/House No, Street Name and Building Name will be automatically populated. Otherwise, please fill in details accordingly
c. Click on "**Save**" and "**Next**" to proceed to the next section
d. If there is more than one manufacturer, click on "**New**" to add particulars of new manufacturer after filling up and saving the details of the first record, before proceeding to the next section.

(4)   Section 4: Particulars of product

* PLEASE FILL IN THE PRODUCT DETAILS IN <u>ENGLISH.</u> Notification not submitted in English may be removed from the HSA notification database without notice.

a. Key in the "**Brand Name**" and "**Product Name**" of your product according to the names appear on the product packaging.
b. Select the "**Type of Product**" that reflects your product type. For example, if you are notifying an anti-wrinkle cream, please select "anti-wrinkle".

* Select the presentation type that best represents your product.

Product presentation type (Please refer to Annex 1 for more details)
c. Single product
   i) Select Presentation Type
       - "**Single Product**"
       - The "**Product Name**" under "**Single Product**" will be automatically populated

*Please click on "**Next**" to proceed to the next section of the product notification after ensuring that the form is filled up properly*

d. A range of variants^V similar in composition for the same use but differs in colours, flavours etc.

^{V}- "Variant" means a cosmetic product preparation that is largely similar in composition to another cosmetic preparation (usually having a common base formulation) but having a different colour, shade, flavour, fragrance or other inherent characteristic apart from the "base formulation", which means a partial cosmetic formulation shared by 2 or more cosmetic preparations manufactured by the same manufacturer and intended for the same use.

Please note that each of the variants should bear the same brand and product name as appear on the product packaging

  i) Select Presentation Type
      • "**A range of variants similar in composition for the same use but differs in colours, flavours etc**"
  ii) Key in the "**No of variants**" in this range
  iii) You will need to key in the "**Variant Name**"
      • To input a new name, click on "**New Variant**"

Please click on "**Next**" to Proceed to the next section of the product notification after ensuring that the forms is filled up properly

e. Palette(s) in a range

Please note that each of the palettes should bear the same brand and product name as appear on the product packaging

Example: Eye Shadow

Var 101	Var 202

Palette One

Var 100	Var 200

Palette Two

No. of Palette Group: 2
No of Variant:
  ✓ Palette One – 2 (Var 101 & Var 202)
  ✓ Palette Two – 2 (Var 100 & Var 200)

i) Select Presentation Type
- "**Palette(s) in a range of one product type**"

ii) Key in the "**No of Palette Group**" in this range of palettes

iii) You will need to key in the "**Palette Name**", followed by the "**No of Variants/ Component**"
- To input a new variant name, click on "**New Variant**"
- To key in the details for the subsequent palettes, click on "**Save Palette**", followed by "**New Palette**"

*Please click on "**Next**" to Proceed to the next section of the product notification after ensuring that the forms is filled up properly*

f. Combination products in a single kit

Example: Festive X'mas Special set containing:
- ✓ 1 Eye Mask (single product)
- ✓ 1 Face Mask (single product)
- ✓ Lip stick (a range of variants with 4 colours)
- ✓ Blusher (a palette with 4 colours)

- Please key in the "**Brand Name**" and "**Product Name**" as appears on the packaging of the combination kit
- Select Presentation Type as "**Combination products in a single kit**"
- Key in the "**No of Single Products**", "**No of Range**" and "**No of Palette**" respectively

i) Single product section

- Key in the "**Product Name**" of the "**Single Product**" as appears on the product packaging
- Select the "**Type of Product**"
- To key in the details for the subsequent single product (if any), click on "**Save Product**", followed by "**New Product**"

ii) Range(s) of variants section

- Key in the "**Range Name**" as appears on the product packaging
- Select the "**Type of Product**"
- Key in the "**No of Variants**"

- To input a new variant name, click on "**New Variant**"
- To key in the details for the subsequent range, click on "**Save Range**", followed by "**New Range**"

iii) Palette(s) in a range section

- Key in the "**Palette Name**" as appears on the product packaging
- Select the "**Type of Product**"
- Key in the "**No of Variants**"
  - To input a new variant name, click on "**New Variant**"
  - To key in the details for the subsequent range, click on "**Save Palette**", followed by "**New Palette**"

*Please click on "**Next**" to Proceed to the next section of the product notification after ensuring that the forms is filled up properly.*

(5)   Section 5: Supporting document(s)

PQ1001 APPLICATION FOR COSMETIC PRODUCT NOTIFICATION

Fill in the application form		Guideline	Help

1. Particulars of Local Company Responsible for Placing the Cosmetic Product in the Market
2. Particulars of Person authorised to represent the local company
3. Particulars of Manufacturer

4. Particulars of Product
5. **Supporting Attachments**
6. Confirmation

Special Symbol   Attach   Save

Previous Next

Fields marked with an asterisk * are mandatory.

5. Supporting Attachments

No attachment is required

Previous Next Reset

a. No supporting attachment is required
b. Click on "**Next**" to proceed to the next section

(6)   Section 6: Declaration, validation, confirmation and payment

Please ensure that data entered are correct as there is **NO** refund once the notification is successfully submitted.

Declaration	
1.	I undertake to abide by the following conditions: i. Ensure that the product's technical and safety information is made available to the regulatory authority concerned ("The Authority") and to keep records of the distribution of the products for product recall purposes; ii. Notify the Authority of fatal or life threatening serious adverse event* as soon as possible by telephone, facsimile transmission, email or in writing, and in any case, no later than 7 calendar days after first knowledge; iii. Complete the Adverse Cosmetic Event Report Form** within 8 calendar days from the date of my notification to the Authority in para 2ii. above, and to provide any other information as may be requested by the Authority; iv. Reports to the Authority of all other serious adverse events that are not fatal or life threatening as soon as possible, and in any case, no later than 15 calendar days after first knowledge, using the Adverse Cosmetic Event Report Form; v. Notify the Authority of any cha fication; vi. Ensure that if and when direc from the market, and discontinue selling or supplying the product
2.	I declare that the particulars giv information of relevance in relation to the notification have been supplied ntic or true copies.
3.	I understand that I shall be resp of my product continues to meet all the legal requirements, and conforms to oduct that I have declared to the Authority.
4.	I understand that I cannot place notification by the authority in any legal proceedings concerning my prod d to conform to any of the standards or specifications that I had previously declared to the Authority.

> **Message from webpage** [X]
>
> ⚠ Validation is successful
>
> [OK]

I agree ⦿ I disagree ○

* As defined in the Guide Manual for the Industry on Adverse Event Reporting of Cosmetics Products
** Set out in Appendix | to the Guide Manual for the Industry on Adverse Event Reporting of Cosmetics Products

Payment Advice		
Sn **Description**	**Amount (SGD)**	**GST**
1 Notification Low Risk Cosmetic Product	10.00	N
The total payment for your notification is SGD **10.00**.		
The amount of SGD **10.00** will be deducted from your Giro Account.		

Please click the Show Printer Friendly Version *button to print this page for filing*

[Show Printer Friendly Version]   [Previous] [Validate] [Submit] [Reset]

a. Read through the "**Declaration**" section and select "**I agree**".
b. Print a copy of the product notification via "**Show Printer Friendly Version**"
c. Proceed to "**Validate**" the submission.
d. The pop up box will indicate that the validation of the product notification is successful.
e. Proceed to "submit" the notification
f. You will be prompted for "**ePayment**" if your company is not on GIRO
g. Select "**Submit**" to make payment via credit card
h. You will be prompted to select your preferred payment mode
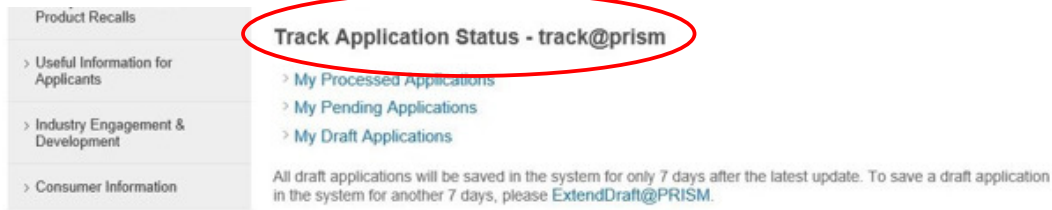
i.   Upon successful submission of the cosmetic product notification, you will receive an **Acknowledgement of Notification**, which will show:
   • Company name & address
   • Brand name & product name
   • Product notification number and validity dates

j.   Print a copy of the Acknowledgement of Notification via "**Show Printer Friendly Version**"

Please note that the product notification is valid for <u>ONE</u> year. Subsequent retention of notification (renewal) is required every year if your company intends to continue marketing the product in the local market.
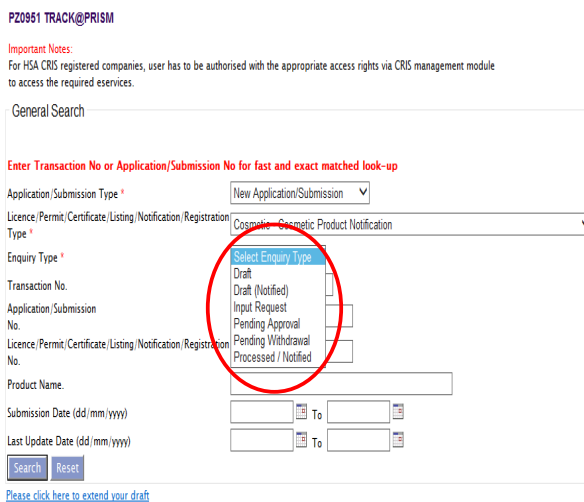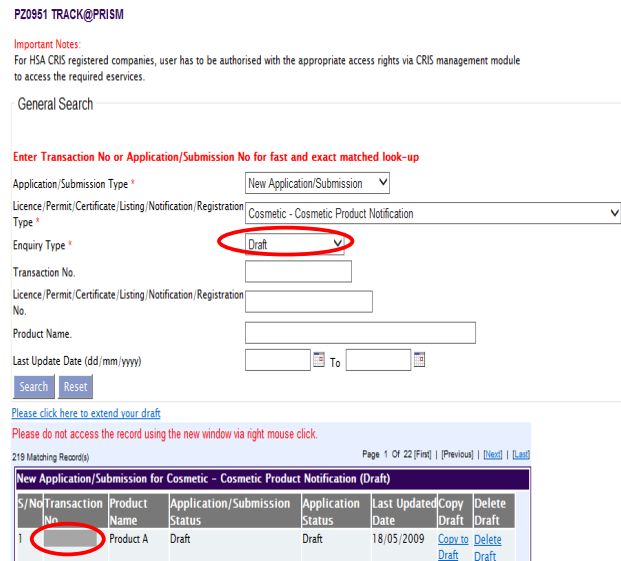
Other Functions in PRISM

(i) Track Application status - Track@PRISM

a. **Functions of** "**Track@PRISM**"
- To retrieve a draft application
- To enquire on a successfully submitted cosmetic product notification

Retrieving Draft Application

c. **To retrieve a draft application**
- Click on "My Draft Applications". You will be prompted to log in via CorpPass, SingPass (ends on 31 Dec 2017) or HSA Pin
- Select "**Enquiry Type**" as "**Draft**"
- Click on "Search" to view all drafts
- For a draft application which has not yet been submitted, a "**Transaction Number**" starting with "T" is as shown

Copy to Draft

The "**Copy to Draft**" function allows companies to retrieve a draft copy of a successfully submitted cosmetic product notification. Companies may amend relevant sections of the form before submitting a subsequent cosmetic product notification of another cosmetic product. This speeds up the submission process.

d. **Copy to Draft**
- Click on "My Processed Applications". You will be prompted to log in via CorpPass, SingPass (ends on 31 Dec 2017) or HSA Pin
- Select **Application/Submission Type** as **"New Application/ Submission"** and "**Enquiry Type**" as "**Processed/Notified**" and the key in the application number. Click on "Search"
- Click on "Copy to Draft". Edit/amend accordingly the details of the second product at the relevant sections before the final submission

(ii) Cancel Notification - Cancel@PRISM

a. **Functions of "Cancel@PRISM"**
- To retrieve and cancel cosmetic product notification that was successfully submitted

If your company is no longer marketing a particular cosmetic product, you may cancel the cosmetic product notification via "**Cancel@PRISM**" before the expiry date of the notification.

Please select the notification(s) you wish to cancel and click on "Cancel" after logging into Cancel Cosmetic Product Notification.

(iii) <u>Re-notification - Renew@PRISM</u>

      a. **Auto Renewal Preference for payment via GIRO**

- Please log into "**Auto Renewal Preference**" to select "**NO**" to renew <u>30 days before date of expiry of notification.</u> There will be no refund once the deadline is passed.
- For companies which wish to retain the notifications (renew), the notifications will be automatically retained/renewed if companies do not log into the system to select "No" to renew.

b. **For companies which are not paying via GIRO**

- Please log into "Cosmetic Product Re-notification" and select product notifications that your company intends to renew
- You will be prompted for "**ePayment**"
- Select "**Submit**" to make payment via credit card
- You will be prompted to select your preferred choice of epayment

For companies which wish to apply for a GIRO Account with HSA to facilitate the payment process, the application form for Interbank GIRO can be downloaded via the following website:
http://www.hsa.gov.sg/content/hsa/en/e-Services.html

(iv) <u>Update of Manufacturer's Details</u> (refer to step-by-step guide on update of manufacturer's details for more information)

      a. Companies can update the changes of the manufacturer's details using the "Update of Manufacturer's Details"

      b. Companies may select up to 20 affected notifications for any amendment submitted.

A **NEW** product notification is required if there is a change made to any of the following:
1) Brand Name
2) Product Name
3) Product Type
4) Formulation
5) Company change due to change of distribution rights
6) Company name change with a new UEN number given by ACRA

Helpdesk Contact

If you require any technical assistance regarding PRISM and cosmetic product notification, please contact the Helpdesk at:
Tel: 67760168
Email: helpdesk@hsahelp.gov.sg

Please indicate the problem areas according to
a) Client Registration & Identification Service (CRIS)
b) Pharmaceutical Regulatory Information System (PRISM)

The information in this Guideline shall be updated or revised from time-to-time. For any new, addition, amendments or deletion made to this Guideline, please refer to the latest version in our website www.hsa.gov.sg.

<div align="right">**Annex 1**</div>

Product Presentation Types

- **Single product** exists in a single presentation form.

- **A range of variants similar in composition for the same use but differs in colours, flavours etc**

  Refers to a range of cosmetic products which are similar in composition and produced by the same manufacturer, and are intended for the same use but are available in different shades or flavours.

  Examples: lipsticks, eye shadows or nail polish but not composite packs of different types

- **Palette(s) in a range of one product type**

    Refers to a range of colours as defined above, which may be presented in a series of palettes.

    A single palette

    Range of palettes

- **Combination products in a single kit**

    Refers to similar and/or different product types packed and sold in a single kit. They cannot be sold separately (e.g. a make-up kit of eye and lip colours; a set of skin-care products sold in a single kit).

    Make-up kit

    Skin Care Kit